

July 18, 1997

Docket Number 95S-0158
Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr., Rm. 1-23
Rockville, MD 20857

RE: **IDE Number G960214/10**

CardioLogic VEST-CPR[®] System 6 '97 OCT -2 P12 :04
Public Disclosure Ad Copy - Medical College of Virginia (MCV) '97

Dear Sir/Madam:

In accordance with 21 CFR §50.25, we are enclosing a copy of the second public disclosure ad in the Richmond Times-Dispatch for the Committee on the Conduct of Human Research approved clinical trial at the Virginia Commonwealth University/Medical College of Virginia under IDE #G960214.

If there are any questions concerning this information, please contact me at 410/691-5200, ext.45.

Sincerely,



Timothy R. Placek
Director of Regulatory Affairs
and Quality Assurance
Official Correspondent

Attachments: 1. Public disclosure ad copy from Richmond Times-Dispatch

95-S-0158

sub 11

CARDIOLOGIC SYSTEMS, INC.

**IDE Number G960214
Supplement Number 10
July 18, 1997**

VOLUME 1

**SPONSORED BY:
CARDIOLOGIC SYSTEM, INC.
7455-T NEW RIDGE ROAD
HANOVER, MARYLAND, USA 21076-3143**



...of both...
 ...g, low-grade infec-
 ...its damage slowly
 ...ain evidence so far
 ...ies that follow large
 ...ple to see whether
 ...ad gums fare differ-
 ...e v don't. The
 ...int u... people with
 ...ase have a higher
 ...of heart attacks.
 ...st impressive is the
 ...Aging Study in Bos-
 ...followed 1,231 men

...especially knotty public health prob-
 ...lem. About 250,000 infants are born
 ...premature and dangerously small in
 ...the United States each year; prema-
 ...turity is by far the leading cause of
 ...newborn deaths.
 ...Doctors have long noticed that
 ...women with bad teeth seem more
 ...likely to give birth prematurely. Of-
 ...fenbacher studied 124 women and
 ...found those with gum disease were
 ...about eight times more likely than
 ...usual to deliver dangerously small
 ...premature babies.



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 ...1. Enter through the east entrance.
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VIRGINIA COMMONWEALTH UNIVERSITY/MEDICAL COLLEGE OF VIRGINIA VEST-CPR STUDY

Virginia Commonwealth University/Medical College of Virginia anticipates that it will be participating in an investigational study to evaluate a new VEST-CPR resuscitation device. The study is being conducted under a recent ruling by the FDA which allows that under strict circumstances, patients in life threatening situations (and for whom there is no one available to give their consent) may be given experimental treatment, if there is no acceptable alternative with a good chance of success. The new technology consists of a vest device that can be wrapped around the chest. If a person's heart stops beating, rhythmic inflation and deflation of the vest with air can maintain circulation until the heart can be restarted. Thus, the device is designed to replace the chest compressions of conventional cardiopulmonary resuscitation (CPR).

In the event that a person's heart stops beating suddenly and unexpectedly while in the hospital, all appropriate means (including standard medications and techniques) will be used to return the normal heart beat. During the study, some persons will have chest compressions performed by the vest device.

The current investigation is designed to compare results with this device vs. conventional CPR in terms of the number of lives saved and any possible adverse effects such as injury to the chest or other structures. Results of this study will be used by the Food & Drug Administration to determine whether the device will be approved for sale in the United States.

Public comments on the proposed investigation are welcomed and should be directed in writing to both:

Joseph P. Ornato, MD
 Dept. of Emergency Medicine
 Virginia Commonwealth University/Medical College of Virginia
 Box 980525
 Richmond, VA 23298-0525

Robert L. Campbell, DDS
 Chairman, Committee on Human Research
 Virginia Commonwealth University/Medical College of Virginia
 Box 980566
 Richmond, VA 23298-0525

Institute for Research and Technology
200 Hawthorne Lane
Post Office Box 33549
Charlotte, NC 28233-3549
(704) 384-5369 FAX (704) 384-5638
<http://www.presbyterian.org>

May 19, 1997

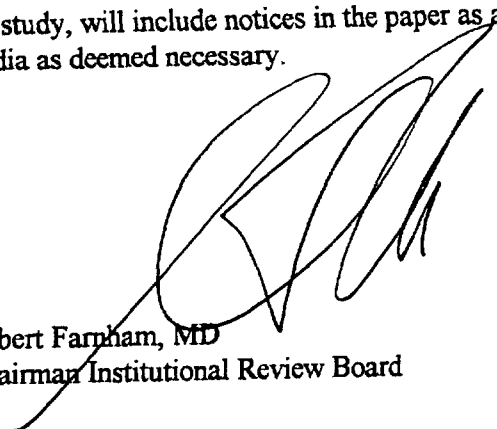
**PLAN OF PUBLIC DISCLOSURE
PRESBYTERIAN HOSPITAL
INSTITUTIONAL REVIEW BOARD
CHARLOTTE, NC**

The following activities will be initiated in order to notify the public that a clinical trial will be taking place at Presbyterian Hospital regarding VEST-CPR and that informed consent has been waived for this clinical trial.

- A public forum will be held on May 13, 1997 at Presbyterian Hospital for the purpose of disclosing to the public the VEST-CPR protocol, including the background, exclusion/inclusion criteria, risks, potential benefits, implementation, alternatives, cost/compensation, confidentiality, and data to be gathered. A discussion of the FDA guidelines for research without informed consent will also be provided. There will be a question/answer session after the presentations. The public's attendance, participation and comments will be documented. See attached agenda.
- Two notices will be placed in the Charlotte Observer newspaper on a weekend day and a weekday immediately preceding the event. The circulation is greater than 300,000 on a weekend and greater than 200,000 on a weekday in the Charlotte/Mecklenburg area.
- An article describing the study in more depth will be written after an interview with the Foundation coordinating the study. It will be placed in the newspaper immediately prior to the community forum.
- Notices will be faxed to appropriate physician offices, posted in the hospital and medical tower elevators, and sent to the health services distribution list to inform the public of the community forum. The staff in these places will be asked to post the notices in areas where the general public can see them.
- The public's comments will be reviewed prior to application for final approval of the project.
- Large signs will be posted in a prominent place on each hospital unit involved to inform patients/families of the study and the procedure to decline participation. VEST-CPR informative pamphlets will be placed in each patient room on the identified units.
- Further notifications with the public, in an attempt to update them on the progress of *The Whole Approach To Health*.

Page 2

the study, will include notices in the paper as above and potentially other forms of media as deemed necessary.



Robert Farnham, MD
Chairman Institutional Review Board

Hospital wants input on CPR vest

ATTACHMENT 2

To test it, there won't always be time to ask patients' permission

Citizens may ask questions about Presbyterians' project Tuesday at a free forum featuring heart specialists from Mid Carolina Cardiology and representatives of the CPR vest manufacturer, Cardiologic Systems Inc. of Hanover, Md.

"We wanted to have a two-way conversation and a chance for questions and answers," said Diane Whisman, coordinator of the study and executive director of Amicus Research Foundation. The foundation is coordinating the study in collaboration with Mid Carolina Cardiology.

More than 450,000 people die each year of cardiac arrest, Whis-

Please see FORUM/page 3E

Researchers at Presbyterian Hospital would like to see if a new CPR vest works better than manual CPR to revive patients whose hearts have stopped.

But the test would mean trying the vest on patients who are so near death they can't give permission.

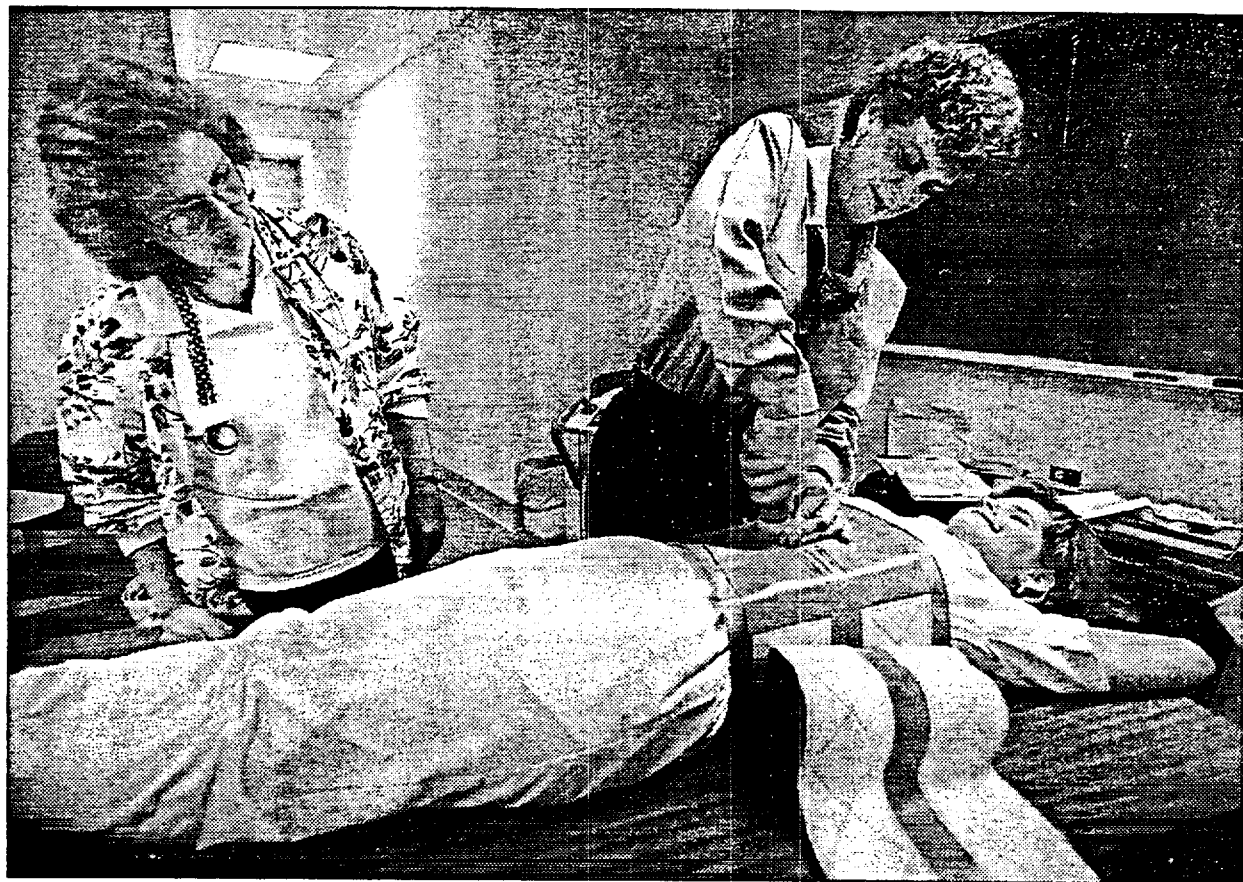
New federal rules allow researchers to waive informed consent when testing treatments in medical emergencies. But the rules also require researchers to make their studies known to the community and seek public comment.

By KAREN GARLOCH
Staff Writer



BOB LEVERONE/Staff

Respiratory therapists Carol Byrd (from left), Gary Baker and Elaine Hartnett (right) leads the mannequin at Presbyterian Hospital. Elaine Hartnett (right) leads the training for the vest's manufacturer, Cardiologic Systems Inc.



BOB LEVERONE/Staff

Presbyterian Hospital's Beverly Foster, a respiratory therapist, watches as Elaine Hartnett of Car-

diologic secures the air hose to a CPR vest modeled by research nurse Andrea Gill.

Hospital wants input on CPR vest

FORUM

Continued from page 1E

matic system that sends air into the vest to compress the whole chest, not just the spot where the palms press in manual CPR. The vest is already used in Europe.

During a demonstration last week, nurses and respiratory therapists wrapped the vest around a mannequin named Fred and attached a plastic hose from the vest to a pneumatic unit beside the bed.

When they pressed a button, air pushed through the tube with a loud puffing sound, inflating the vest and compressing Fred's torso. Quickly, it deflated and inflated again, mimicking the compressions of manual CPR.

But with manual CPR, Whisnant said, "there is a lot of inconsistency in the way people do it."

If the Presbyterian study is approved, patients who qualify will receive either manual CPR or the CPR vest on a random basis.

When possible, hospital employees will try to contact family members to get consent for the patient

to be in the study. Otherwise, patients who survive will be asked later if researchers can use their experience in the study. For patients who don't survive, families will be informed that their relatives were included.

"By coming to this hospital, they will have given consent, unless they tell a nurse on the floor, 'No, I don't want that,'" Whisnant said. "People might get alarmed at that. That's why we want comments."

Presbyterian first tried the experiment 2½ years ago by asking patients to sign consent forms in case they might have cardiac arrest. In six months, only one consenting patient had a cardiac arrest while in the hospital. CardioLogic stopped the study, realizing it would take too long to get enough patients to prove the vest's effectiveness.

Studies have been done before without the consent of patients who weren't able to give it and for whom relatives weren't available. But the new federal rules, which took effect in November, give clear guidelines on how to do it ethically.

Dr. Jeff Runge of Charlotte was one of the emergency medicine

specialists who led the effort to get the regulations passed.

At Carolinas Medical Center, he is heading a recently approved study that also involves an emergency treatment. In that project, critically injured patients who come to the emergency room will receive an experimental product, hemoglobin, in addition to blood transfusions.

To meet the federal requirements on public notification, Carolinas Medical Center advertised for comments from the community in March. It received about 20 letters and phone calls; all but two were supportive.

IF YOU'RE GOING

The free forum on the CPR vest will be at 7 p.m. Tuesday in the Presbyterian Hospital multipurpose room, 200 Hawthorne Lane. To register or leave comments, call 483-2900 any time.

Presbyterian

Forum Explores New CPR Technology

*Free To The
Community*

Mid Carolina Cardiology will present a free community forum regarding the use of a new technology for patients experiencing cardiac arrest. The vest CPR, being studied at Presbyterian Hospital, offers a new and potentially better way to perform CPR. A vest, similar to a blood pressure cuff, is placed around the patient's chest to do compressions. This research hopes to demonstrate increased survival for patients. Under the new federal ruling on waiver of informed consent, community notification is required prior to initiating this research.

Call 483-2900

with comments and to register.

May 13, 1997

7:00 - 8:30 pm

**Presbyterian Hospital
Multipurpose Room**

200 Hawthorne Lane



**Presbyterian
Healthcare System**

Presbyterian Hospital

Presbyterian Hospital Matthews

Presbyterian Hemby Children's Hospital

Presbyterian Specialty Hospital

Presbyterian Orthopaedic Hospital

Presbyterian Healthcare Associates

Presbyterian Health Network

Presbyterian Wesley Care Center

Presbyterian Hospital Foundation

economic change of some kind is badly needed on the continent. Unemployment in Britain is only 5.1 percent, but it's 12.3 percent in France, 12.1 percent in Italy, 11.7 percent in Germany and almost 22 percent in Spain.

But achieving consensus in European countries on what to do about it is all but impossible, in part because the political spectrum is much more fragmented than in Britain. Further, in much of the continent, proportional representation imposes a need for coalition government.

Thatcher disliked consensus, and because of the British electoral system, she won healthy majorities in Parliament even though her Conservatives never won a majority of the popular vote.

Thus she was able to break the stranglehold that British labor unions had over the economy when she arrived in power, and she legislated flexibility in British hiring and firing practices. She was also able to cut British income taxes to a top rate of 40 percent — about what Americans in the upper tax brackets pay on some of their income but far less than what the richest pay in France (54 percent) or in Germany (53 percent).

Two decades later, Blair has accepted most of these Thatcherite prescriptions as essential for Britain to compete effectively in the new global economy.

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Forum Explores New CPR Technology

Mid Carolina Cardiology will present a free community forum regarding the use of a new technology for patients experiencing cardiac arrest. The vest CPR, being studied at Presbyterian Hospital, offers a new and potentially better way to perform CPR. A vest, similar to a blood pressure cuff, is placed around the patient's chest to do compressions. This research hopes to demonstrate increased survival for patients. Under the new federal ruling on waiver of informed consent, community notification is required prior to initiating this research.

Call 483-2900
with comments and to register.

May 13, 1997
7:00 - 8:30 pm

Presbyterian Hospital
Multipurpose Room
200 Hawthorne Lane

Free To The Community


Presbyterian Healthcare System

Presbyterian Hospital
Presbyterian Hospital Matthews
Presbyterian Hemby Children's Hospital
Presbyterian Specialty Hospital
Presbyterian Orthopaedic Hospital
Presbyterian Healthcare Associates
Presbyterian Health Network
Presbyterian Wesley Care Center
Presbyterian Hospital Foundation

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AGENDA

VEST-CPR® PUBLIC FORUM

MAY 13, 1997

- 7:00 pm Welcome/Introductions**
Dr. Kremers, Mid Carolina Cardiology
- 7:05 pm FDA Guidelines and IRB**
Dr. Farnham, Presbyterian Hospital
- 7:20 pm Protocol Review**
Risks & Benefits
Dr. Kremers, Mid Carolina Cardiology
- 7:40 pm Review/Demo Standard CPR**
Presbyterian Hospital
- 7:50 pm Review/Demo VEST-CPR®**
Elaine Hartnett, CardioLogic Systems, Inc.
- 8:00 pm Questions**

QUESTIONS

PLEASE ANSWER A FEW QUESTIONS BY CIRCLING THE APPROPRIATE ANSWER.

1. Age? < 40 <50 50-65 >65

2. Sex? Male Female

3. Race? Caucasian African American Asian Hispanic

Other: _____

4. Occupation? _____

5. Do you work in healthcare? yes no

6. Are you certified in CPR? yes no

7. Have you ever given CPR? yes no

8. Do you know anyone who has received CPR? yes no

9. Have you had any experiences with Presbyterian Hospital? yes no

If yes, in what way? _____

10. Do you approve of this study? yes no

11. Comments: _____

AGE	<40	<50	50-65	>65
	12	6	5	2

SEX	Male	Female
	11	14

RACE	Caucasian	AF Amer	Asian	Hispanic	Other
	24	1	0	0	0

	Sales	Nsg	Retired	Homemkr	Research	Executive	Attorney	Minister	Hltcare adm	EMS	MD	N/AV
OCCUPATION	2	4	1	2	3	1	1	1	2	1	3	4

Yes	No
15	10

WORK IN HLTHCARE

	Yes	No
CERT. IN CPR	12	13

GIVEN CPR	
Yes	9
No	16

	Yes	No
KNOW RECIP. OF CPR	14	11

	Yes	No	N/AV
EXP. WITH PH	19	3	3

APPROVE STUDY	Yes	No
	25	0

Comments:

Inclusion/Exclusion criteria - how long will this take to determine?
Sounds Positive
Great presentation Diane!
Excellent comprehensive program!
This is a great result of interest in the CPR Vest Research of the future.
Have cardiology practices surveyed their patients who
might be likely candidates for this use?
What about asking the Senior Scholars organization and a class held
at the Senior Center?

Should we do research without consent?—
It sounds great! The benefits surely outweigh the risks.
A bit too much "selling" of the machine - needs more explanation of
alternatives, and expected outcome of current manual CPR -
in the brochure; but should be stressed verbally.

[illegible]

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10

QUESTIONS AT COMMUNITY FORUM

- 1) I thought there was no crossover, but you said manual would be used first, then vest ?
- 2) Do you see this eventually reaching out into the field (ie.medics)?
- 3) Is the pressure automatically adjusted or can you regulate it?
- 4) What other kinds of human errors are possible?
- 5) Is the vest for multiple use?
- 6) What kind of power does this use, 110?
- 7) Would the pressure be the same on a child?
- 8) Can you install the vest too snug or too loose?
- 9) If you have a cardiac arrest due to a blood clot in the artery, could the vest push the clot away?
- 10) Has the vest been used on humans?
- 11) It seems like everyone's fascinated with the technology all over the country, what kind of experience is there with the waiver? (It seems like from the public, the technology questions are the ones that come up.)
- 12) From the insight of having undergone CPR, why would people object to its use?
- 13) I can't tell someone that I want to consent if I come to this hospital? I can't say yes I want this when I'm admitted?
- 14) Can't you just make it part of the admission question?
- 15) Why couldn't you go ahead and use it in the ER?
- 16) This study is 2 years or 15 years?
- 17) If successful, how quickly would it go to the next phase and try pre-hospital?
- 18) Will there be a randomized study pre-hospital?
- 19) Given that it will take X amount of time to perform this study, what is the ratio that will receive the vest outside of all the variables mentioned? (ie. #admitted, fit criteria looks like obvious place to do this is in the ER, couldn't this study take a long time?
- 20) Do you get the consensus from the entire medical staff for their patients?
- 21) Will you track the patients beyond the 6 month length of time? Will you not see a major change after 6 months (neurologically)?

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Shipper's name
JOHN HERRON

Address
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MANASSAS VA

Zip code (required)
220763143

Phone/Fax/Telex
14101691-5200

2 To (Recipient)

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